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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ANTHONY E. WICKS, M.D. DECISION and ORDER

On June 6, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Anthony E. Wicks, M.D. (Applicant), of Tampa, Florida. Show Cause Order at 1. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration, because granting his application would be "inconsistent with the public interest." See id.; 21 U.S.C. § 823(f).

The Show Cause Order specifically alleged that in approximately December 2010, Applicant discontinued his practice in Visalia, California and began practicing in Winter Springs, Florida, and that he issued more than 2,290 controlled-substance prescriptions without being registered at this location, in violation of 21 U.S.C. § 822(e) and 21 CFR 1301.12; and that he also failed to notify DEA of the change in his practice location pursuant to 21 CFR 1301.51. Show Cause Order at 1. The Show Cause Order also alleged that after Applicant's registration expired on May 31, 2011, he issued more than 270 controlled-substance prescriptions, in violation of 21 U.S.C. §§ 841(a) and 843(a)(2). <u>Id</u>. at 2.

The Show Cause Order further notified Applicant that within thirty days of the date of his receipt of the Order, he had the right to either request a hearing, or to file a waiver of his right to a hearing, together with a written statement of his position on the matters of fact and law asserted by the Government. <u>Id</u>. (citing 21 CFR 1301.43(a) & (c))._In addition, the Order notified applicant that should he "request a hearing and then fail to appear at the . . . hearing, [he would]

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be deemed to have waived his right to a hearing" and that a final order may be entered "without a hearing based upon the evidence presented to" me. <u>Id</u>. (citing 21 CFR 1301.43(d) & (e)).

The Government served the Show Cause Order on Applicant by certified mail addressed to him at the address of his proposed registered location. GXs 1, 16, 17. As evidenced by the signed return receipt card, service was accomplished on June 9, 2012. GX 17.

On July 5, 2012, Applicant, through his counsel, filed a timely request for a hearing. GX 18. The matter was placed on the docket of the Office of Administrative Law Judges (ALJ) and assigned to an ALJ, who proceeded to conduct pre-hearing procedures. GX 22. However, on September 26, 2012, Applicant withdrew his request for a hearing. GX 21. The same day, the ALJ issued an Order granting Applicant's request and cancelled the hearing. GX 22.

On March 13, 2013, the Government submitted the Investigative Record and a Request for Final Agency Action to my Office. As an initial matter, I find that Applicant, by withdrawing his request for a hearing, has waived his right to a hearing on the allegations. See 21 CFR 1301.43(d). I therefore issue this Decision and Order based on relevant evidence found in the Investigative Record submitted by the Government. See id. 1301.43(e). I make the following findings.

FINDINGS

Applicant previously held DEA Certificate of Registration BW7987184, which authorized him to dispense controlled substances in Schedules II through V, as a practitioner, at the registered address of 400 West Mineral King Blvd., Department of Anesthesia, Visalia, California. GX 2. This registration was issued on April 11, 2008 and expired on May 31, 2011. Id. While Applicant was sent two renewal notices, as well as a delinquency notice (after

¹ Applicant had also previously held a registration which authorized him to dispense controlled substances at the registered location of: Department of Anesthesia, St. Joseph's Hospital, 1105 Shipwatch Circle, Tampa, Florida. GX 4, at 1. This registration expired on May 31, 2005 and was retired when Applicant failed to renew it. <u>Id.</u> at 2.

his registration had expired), he failed to renew the registration, and on July 1, 2011, it was retired by the Agency. GX 3, at 1; GX 15, at 3, \P 11.

On July 19, 2011, Applicant applied for a new registration. GX 1. Applicant sought authority to dispense controlled substances in Schedules II – V at the registered address of 1105 Shipwatch Circle, Tampa, Florida. Id.

A Diversion Investigator (DI) subsequently determined that beginning in December 2010, Applicant had begun practicing at a pain clinic located in Winter Springs, Florida. GX 15. However, Applicant neither obtained a registration for this location, nor sought to modify the address of his then-existing registration. Instead, during the ensuing period, which lasted through at least most of June 2011, Applicant issued 3,120 controlled-substance prescriptions², using DEA registration BW7987184, while listing his address as Pain Management of Winter Springs, 165 W. SR 434, Winter Springs, Florida. GX 15, at 2, ¶¶ 5-6. Applicant never notified the Agency that he had changed his practice address. Id. at 2, ¶ 5.

The DI also found that Applicant had issued at least 341^3 controlled-substance prescriptions after his registration had expired. GX 15, at 2, ¶ 7; see also GX 13. Applicant wrote the prescriptions for oxycodone, diazepam, and lorazepam. GX 15, at 2, ¶ 7; GX 13.

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² Documentary evidence, which the Government acquired through administrative subpoena, includes copies of some of the prescriptions Respondent wrote for controlled substances while practicing at the Winter Springs pain clinic. See GXs 7-11. Walgreens' and Albertsons' pharmacies provided the documents. <u>Id.</u> Additionally, Walgreens provided a chart summarizing all of Applicant's prescriptions that were filled at their pharmacies after he started practicing at the Winter Springs pain clinic. <u>See</u> GX 14.

³ The documentary evidence offered by the Government in support of this figure is contained within GX 13. This exhibit contains 439 pages of documents which were obtained from Walgreens; however, the exhibit contains prescriptions, as well as the labels that were generated for the prescriptions and which are typically placed in the pharmacy's dispensing log. However, even if this exhibit does not support the exact number of controlled substance prescriptions Applicant issued as alleged by the DI, it still provides evidence that he issued several hundred prescriptions after the expiration of his registration. Moreover, in Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 519, 77 FR 62315, 62316, 62328 (2012), I adopted the ALJ's finding that these stores had dispensed a total of 55 controlled-substance prescriptions for oxycodone 30mg, which Applicant issued after the expiration of his registration.

DISCUSSION

Under the Controlled Substances Act (CSA), an application for a practitioner's registration may be denied if "the issuance of such registration ... would be inconsistent with the public interest." 21 U.S.C. § 823(f). In making the public interest determination, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority;
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances;
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances; and
- (5) Such other conduct, which may threaten the public health and safety.

21 U.S.C. § 823(f).6

"[T]hese factors are considered in the disjunctive." Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. Id. Moreover, while I "must consider each of these factors, [I] 'need not make explicit findings as to each one." MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2011) (quoting Volkman v. DEA, 567 F.3d 215, 222 (6th Cir. 2009)); see also Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005) (citing Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005)).

The Government has "the burden of proving that the requirements for . . . registration . . . are not satisfied." 21 CFR 1301.44(d). In this matter, I have considered all of the factors and

⁴ Oxycodone is a schedule II controlled substance. <u>See</u> 21 CFR 1308.12(b)(1).

⁵ Both Diazepam (Valium) and Lorazepam (Ativan) are schedule IV depressants. 21 CFR 1308.14(c).

⁶ Pursuant to 21 U.S.C. § 871(a), the Attorney General has delegated this authority to the DEA Administrator. <u>See</u> 28 CFR 0.100(b).

conclude that the evidence with respect to factors two and four supports the conclusion that granting the application "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

Factors Two and Four – Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Federal and State Laws Related to Controlled Substances

A. The Applicant's Issuance of Prescriptions at an Unregistered Location

Under the CSA, "[e]very person who dispenses⁸ . . . any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." 21 U.S.C. § 822(a)(2). Moreover, "[a] separate registration [is] required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances." Id. § 822(e); see 21 CFR 1301.12(a).

In a rulemaking, DEA has explained that "DEA individual practitioner registrations are based on a [s]tate license to practice medicine and prescribe controlled substances." DEA, Clarification of Registration Requirements for Individual Practitioners, 71 FR 69478 (2006) (final rule); see also 21 U.S.C. § 823(f) ("The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."). Therein, the Agency further

⁷ It is acknowledged that the Government offered no evidence regarding factors one, three, and five. While I have assumed that there is no evidence under any of these three factors that would support the denial of Applicant's application, the Agency has held that findings under a single factor can support the denial of an application. See MacKay, 664 F.3d at 817-18 (quoting Dewey C. MacKay, 75 FR 49956, 49973 (2010)); see also Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); Jayam Krishna-Iyer, 74 FR 4590, 462 (2009).

⁸See 21 U.S.C. § 802(10) ("The term 'dispense' means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance").

⁹ See also 21 U.S.C. § 802(21) (defining "[t]he term 'practitioner' [as] a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance in the course of professional practice"); <u>id.</u> § 824(a)(3) (authorizing the suspension or revocation of a registration based "upon a finding that the registrant . . . has had his State license or registration

explained that "[s]tate authority to conduct the above-referenced activities only confers rights and privileges within the issuing State; consequently, the DEA registration based on a [s]tate license cannot authorize controlled substance dispensing outside the State." 71 FR at 69478.

The evidence shows that Applicant issued thousands of controlled-substance prescriptions while practicing medicine at the Winter Springs, Florida pain clinic and did so over the course of a seven-month period. The evidence thus establishes that Applicant maintained a principal place of professional practice at the Winter Springs pain clinic. Because the evidence further shows that during this period, Applicant was not registered at this location, or any other location in the State of Florida, I conclude that Applicant violated the CSA's separate registration requirement. 21 U.S.C. § 822(e). 10

The CSA further provides that "[e]very registrant . . . shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require." 21 U.S.C. § 827(g). Under a DEA regulation, "[a]ny registrant may apply to modify his/her registration . . . to change his/her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration." 21 CFR 1301.51. Of consequence, this regulation further provides that "[t]he request for modification shall be handled in the same manner as an application for registration." Id. Moreover, under 21 CFR

suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the ... dispensing of controlled substances").

¹⁰ As support for its contention that, "[u]nder DEA regulations, a practitioner is required to report a change of registered address to DEA," the Government cites 21 CFR 823(f)(2). Request for Final Agency Action, at 6. However, a review of the Code of Federal Regulations reveals that the provision cited by the Government does not even exist, and to the extent the Government mistakenly cited to the Code of Federal Regulations rather than the United States Code, 21 U.S.C. § 823(f)(2) provides no support for its contention because it is simply a factor to be considered in determining the public interest and is not an independent requirement for registration. See Penick Corp., Inc., v. DEA, 491 F.3d 483, 490 (D.C. Cir. 2007) (citation omitted). Indeed, the text of factor two simply directs the Agency to consider "[t]he applicant's experience in dispensing . . . controlled substances" and imposes (unlike numerous other provisions of the CSA) no substantive obligation on an applicant or registrant.

1301.13(a), "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person."

Because section 827(g) clearly creates a substantive obligation on the part of a registrant to notify the Agency if he changes his professional address, the regulation's use of the words "may apply to modify" cannot alter (and cannot reasonably be read as altering) the binding nature of a registrant's obligation to notify the Agency. Cf. Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 842-43& n.9 (1984); see also United States v. Marte, 356 F.3d 1336, 1341 (11th Cir. 2004) ("When a regulation implements a statute, the regulation must be construed in light of the statute[.]") (citation omitted). Indeed, because the regulation itself further states that a modification is "handled in the same manner as an application for registration," and thus, a registrant may "not engage in any activity for which registration is required until the application ... is granted and a ... [r]egistration is issued," 21 CFR 1301.13(a), the regulation is also properly construed as imposing, on a registrant who changes his professional address, the binding obligations to both: 1) notify the Agency, and 2) refrain from dispensing activities until his request is approved. Accordingly, I also conclude that Respondent violated the CSA and DEA regulations when he failed to notify the Agency of the change of his professional address and yet proceeded to dispense controlled substances at his new practice location. See 21 U.S.C. § 827(g); 21 CFR 1301.13(a) and 1301.51. These findings, particularly when considered in light of the extent of the Applicant's violations, support the conclusion that granting Applicant's application "would be inconsistent with the public interest." <u>Id.</u> § 823(f).

B. The Applicant's Issuance of Prescriptions After His DEA Registration Expired

Under the CSA, it is unlawful for a practitioner to "knowingly or intentionally . . . use in the course of the distribution[] or dispensing of a controlled substance, . . . a registration number which is . . . expired." 21 U.S.C. § 843(a)(2); see also 21 CFR 1306.03(a) ("A prescription for a controlled substance may be issued only by an individual practitioner who is . . . registered"). Notably, a DEA Certificate of Registration states on its face the date it expires; with respect to Applicant, his registration stated that it expired on May 31, 2011. See GX 2. Moreover, other evidence submitted by the Government shows that the Agency sent notices (on March 25 and April 10, 2011) to Applicant notifying him of the impending expiration of his registration. GX 3, at 2.

Here, the evidence shows that while Applicant's registration expired on May 31, 2011, he nonetheless proceeded to use the registration to issue several hundred controlled-substance prescriptions for drugs such as oxycodone 30mg. and Valium 10mg. See GX 13. In the absence of any evidence to the contrary, I further find that Applicant knew that his registration had expired and thus violated the CSA and DEA regulations when he continued to use it to issue the prescriptions. 21 U.S.C. § 843(a)(2); 21 CFR 1306.03(a).

Here again, the extent of Applicant's misconduct in using an expired registration to issue prescriptions provides reason to deny his application. See Larry E. Davenport, M.D., 68 FR 70534, 70537-38 (2003), pet. for rev. denied Davenport v. U.S. Dep't of Justice, 122 F. App'x 224 (6th Cir. 2005); James C. LaJevic, D.M.D., 64 FR 55962, 55964 (1999). These violations, coupled with the thousands of violations Applicant committed in issuing prescriptions at the Winter Springs pain clinic without being registered at this location, strongly support the conclusion that granting Respondent's application for a new registration "would be inconsistent"

with the public interest." 21 U.S.C. § 823(f). Accordingly, I will order that Applicant's application be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Anthony E. Wicks, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective immediately.

Dated: September 30, 2013 Thomas M. Harrigan
Deputy Administrator

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